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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12178192/VPA/PXK/wm	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001487	International Filing Date (day/month/year) 10 November 2003	Priority Date (day/month/year) 8 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C12N 15/11 C12N 15/12 C12N 15/29 C12N 15/66 C12Q 1/68		
Applicant THE UNIVERSITY OF QUEENSLAND et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 2 June 2004	Date of completion of the report 25 February 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer DAVID OLDE Telephone No. (02) 6283 2569

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001487

1. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.☒ the description, pages 1-34, as originally filed,
pages , filed with the demand,
pages , received on with the letter of☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 35-39, received on 8 February 2005 with the letter of 8 February 2005☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of☒ the sequence listing part of the description:
pages 1-44, as originally filed
pages , filed with the demand
pages , received on with the letter of2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/fig.5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

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International application No.

PCT/AU2003/001487

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-38	YES
	Claims -	NO
Inventive step (IS)	Claims 1-38	YES
	Claims -	NO
Industrial applicability (IA)	Claims 1-38	YES
	Claims -	NO

2. Citations and explanations (Rule 70.7)

The invention is seen to reside in methods of generating synthetic polynucleotides able to alter a selected phenotype of an organism from the phenotype conferred by the native polynucleotide encoding a polypeptide. This is carried out by selecting codons of the parent polynucleotide and replacing them with synonymous codons selected based on conferring a different phenotypic preference to the original in a test organism. The first codon is then replaced by the selected synonymous codon to produce the synthetic polynucleotide. The invention appears to relate to the selection of codons, not for translational efficiencies in particular cells or tissues, but for codons having optimal preferences of usage by an organism for producing a selected phenotype, wherein the selected phenotype is other than a phenotype that is conferred upon a cell by a polynucleotide that is expressed in the cell and that encodes a polypeptide associated with producing the phenotype.

The following citations have been considered for the purposes of this opinion:

D1: WO 2000042215

D2: WO 2000042190

D3: WO 1999002694

D4: Kawakami *et al*D5: Stenström *et al*Novelty (N) and Inventive Step (IS)

The claimed invention is considered novel and inventive in light of D1-D5 as the claimed invention is not disclosed or suggested by these citations.

Industrial Applicability (IA)

Claims 1-38 meet the requirements of the PCT in terms of industrial applicability.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 16 is not clear. There is no antecedent for the phrase "tandem repeat" in claim 1.

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